IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG	)	
Plaintiffs,	)	Civil Action No.
v.	)	
RANBAXY INC. and RANBAXY LABORATORIES LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Ranbaxy Inc. and Ranbaxy Laboratories Ltd. ("Ranbaxy Ltd.") (collectively "Ranbaxy") allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Ranbaxy with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07396.

3. Plaintiff Novartis AG ("Novartis AG") is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056, Basel, Switzerland.

4. Upon information and belief, Ranbaxy Inc. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 600 College Road East, Princeton, New Jersey 08540.

5. Upon information and belief, Ranbaxy Laboratories Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 12th Floor, Devika Towers, 6 Nehru Place, New Dehli, India.

6. Upon information and belief, Ranbaxy Inc. is a wholly-owned subsidiary of Ranbaxy Ltd., is controlled by Ranbaxy Ltd., and acts as the U.S. agent for Ranbaxy Ltd. in connection with the sale of pharmaceutical products in the United States, including in the State of Delaware and this judicial district.

JURISDICTION AND VENUE

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, this Court has personal jurisdiction over Ranbaxy Inc. and Ranbaxy Ltd.

10. Upon information and belief, Ranbaxy Inc. and Ranbaxy Ltd. are in the business of developing and manufacturing generic and branded pharmaceutical products.

11. Upon information and belief, Ranbaxy Inc. and Ranbaxy Ltd. directly, or indirectly through their subsidiaries and/or distributors, market, distribute, and sell their generic

and branded pharmaceutical products within and throughout the United States, including in the State of Delaware and throughout this judicial district.

12. Upon information and belief, this Court has personal jurisdiction over Ranbaxy Inc. because Ranbaxy Inc. purposefully avails itself of the privilege of doing business in the State of Delaware by being formed and existing under the laws of Delaware and continuously and systematically placing goods in the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling directly or through its agents, pharmaceutical products in the State of Delaware. Upon information and belief, this Court also has personal jurisdiction over Ranbaxy Inc. because it has appointed and authorized an agent to accept service of process in Delaware.

13. Upon information and belief, this Court has personal jurisdiction over Ranbaxy Ltd. because Ranbaxy Ltd., through its wholly-owned subsidiary and agent Ranbaxy Inc., markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

14. Upon information and belief, this Court also has personal jurisdiction over Ranbaxy Ltd. because it purposefully avails itself of the privilege of conducting activities within the State of Delaware, including by causing its wholly owned subsidiary Ranbaxy Inc. to be incorporated in Delaware.

15. Upon information and belief, this Court also has personal jurisdiction over Ranbaxy Inc. and Ranbaxy Ltd. because they have been sued previously in this district, did not challenge this Court's assertion of personal jurisdiction over them, and availed themselves of this forum by seeking affirmative relief in this jurisdiction by answering Complaints and asserting

counterclaims for the purpose of litigating a patent infringement dispute in at least eight cases since 2013, including, without limitation: *Acura Pharmaceuticals Inc. v. Ranbaxy Inc. et al.*, No. 13-cv-00750-RGA (D. Del. filed Apr. 29, 2013); *UCB Inc. et al. v. Ranbaxy Laboratories Ltd. et al.*, No. 13-cv-01215-LPS (D. Del. filed July 10, 2013); *Forest Laboratories Inc. et al. v. Ranbaxy Inc. et al.*, No. 13-cv-01607-SLR (D. Del. filed Sept. 23, 2013); *Teijin Limited et al. v. Ranbaxy Laboratories Limited et al.*, No. 14-cv-00117-SLR (D. Del. filed Jan. 31, 2014); *Forest Laboratories Inc. et al. v. Ranbaxy Inc. et al.*, No. 14-cv-00686-LPS (D. Del. filed May 30, 2014); *Avanir Pharmaceuticals Inc. v. Ranbaxy Laboratories Limited et al.*, No. 14-cv-00792-LPS (D. Del. filed June 20, 2014); *Shire LLC et al. v. Ranbaxy Inc. et al.*, No. 14-cv-00827-RGA (D. Del. June 25, 2014); and *Endo Pharmaceuticals Inc. et al. v. Ranbaxy Laboratories Ltd. et al.*, No. 14-cv-1386-RGA (D. Del. filed Nov. 7, 2014).

16. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b).

THE PATENTS IN SUIT

17. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

18. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

19. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

20. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

21. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

22. By letter dated November 19, 2014 ("Ranbaxy's Notice Letter"), Ranbaxy notified Novartis that it had submitted ANDA No. 206723 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief, Ranbaxy stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

23. Upon information and belief, both Ranbaxy Inc. and Ranbaxy Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206723.

24. As stated in its Notice Letter, Ranbaxy's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and/or sale of Ranbaxy's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. On information and belief, Ranbaxy intends to engage in the commercial manufacture, use and/or sale of its ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

25. In its Notice Letter, Ranbaxy notified Novartis that its ANDA contained a "paragraph IV certification" that in Ranbaxy's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of Ranbaxy's Imatinib Mesylate ANDA Tablets.

26. Ranbaxy's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

27. Ranbaxy's commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

28. Upon FDA approval of Ranbaxy's ANDA, Ranbaxy will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and/or selling its Imatinib Mesylate ANDA Capsules in the United States unless enjoined by this Court.

29. Ranbaxy had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

30. Novartis will be substantially and irreparably damaged and harmed if Ranbaxy's infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Ranbaxy has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Ranbaxy's making, using, selling, offering to sell or importing its Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Ranbaxy to make, use or sell its Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Ranbaxy from making, using, selling, offering to sell, or importing its Imatinib Mesylate ANDA Tablets until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Ranbaxy engages in the commercial manufacture, use or sale of its Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: December 29, 2014

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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